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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/872,135

05/31/2001

Brandon James Yoe

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07/22/2009

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EXAMINER

NGUYEN, CAMTU TRAN

ART UNIT

PAPER NUMBER

3772

MAIL DATE

DELIVERY MODE

07/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/872,135	YOE ET AL.	
	Examiner	Art Unit	
	Camtu T. Nguyen	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-7,10-12,21-25,27-32 and 73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-7,10-12,21-25,27-32 and 73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/25/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 2/25/2009. Claims 2, 4, 8-9, 13-20, 33-72, and 74-85 have been canceled. Claim 26 have been withdrawn from consideration as result of the restriction requirement (4-6-2006).

In reviewing the prosecution history of this instant application, it is noted that applicant's Declaration Under Rule 131 was not properly treated. The Examiner wishes to response to it here for record.

Declaration

The Declaration filed on 6/28/2005 (signed copies filed 9/20/200 under 37 CFR 1.131 has been considered but is ineffective to overcome the Hoissainy et al reference (6,764,505).

The declaration did not explain which facts in the pages supplied therewith prove conception, diligence, and/or an actual reduction to practice and how the facts establish the alleged facts.

The 37 CFR 1.131 affidavit or declaration must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed genus), in the sense that the claim as a whole reads on it. In re Tanczyn, 347 F.2d 830, 146 USPQ 298 (CCPA 1965). With this in mind, among other items, the declaration does not show possession of therapeutic agent gradually decreases a location inward of a

proximal end to/at proximal end of elongated source or from a location inward of a distal end to/at the distal end of elongate source.

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Hoissany et al reference to either a constructive reduction to practice or an actual reduction to practice. Applicant submitted activities occurred only on June 13 & 14, 2000. What is meant by diligence is brought out in *Christie v. Seybold*, 1893 C.D. 515, 64 O.G. 1650 (6th Cir. 1893). In patent law, an inventor is either diligent at a given time or he is not diligent; there are no degrees of diligence. An applicant may be diligent within the meaning of the patent law when he or she is doing nothing, if his or her lack of activity is excused. Note, however, that the record must set forth an explanation or excuse for the inactivity; the USPTO or courts will not speculate on possible explanations for delay or inactivity. As such, applicant's declaration provided insufficient evidence to establish diligence.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Hossainy et al reference. Specifically, the evidence submitted was eluded to animal clinical studies rather than to establish a reduction to practice of the invention prior to effective date of the Hossainy et al reference.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5-7, 10-12, 21-25, 27-29, 31-32, and 73 are rejected under 35

U.S.C. 102(e) as being anticipated by Hossainy et al (U.S. Patent No. 6,764,505).

Hossainy et al discloses in Figure 1-9 a stent comprising elements as recited in these claims including a body having a first end and a second end and a middle segment between the first and the second ends, a variable stent surface per unit length of the body wherein the first and the second ends have a lesser surface area than the middle segment, and a drug deposited on the stent so that the first and the second ends have a lesser amount of the drug than the middle segment.

Hossainy discloses in column 2 lines 32-39 that the intensity of radiation decreases as the source of the radiation, the radioactive stent, terminates at its ends leading to a drop of in radiation levels at vessel portions adjacent its ends. Thus, the Hossainy stent, would inherently include a non-therapeutic level of radioactivity at its ends.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al (U.S. Patent No. 6,764,505). Hossainy et al discloses in Figure 1-9 a stent comprising elements as recited in these claims but does not teach the dose of the radioactivity comprises up to 60 Gray. Turnlund et al teaches in paragraph [0043] a dose of radiation of between 1 Gy and about 50 Gy. Therefore it would have been obvious to one skilled in the art to use the Hossainy et al's stent having an amount radiation dose of radiation as suggested by Turnlund et al as such has been shown to induce thrombus formation along the interior surface, which is the initial step towards endothelialization for the lumen interior surface, proliferative cellular healing can commence.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772